

(2) The extent of service and quality competition among the domestic manufacturers for shares of the domestic market including:

(i) Shifts in market shares and

(ii) Shifts in individual customers among domestic manufacturers;

(3) The existence of substantial differentials between domestic prices and the higher of prices generally prevailing in foreign markets or the prices at which the applicant for registration to import is committed to undertake to provide such products in the domestic market in conformity with the Act. In determining the existence of substantial differentials hereunder, appropriate consideration should be given to any additional costs imposed on domestic manufacturers by the requirements of the Act and such other cost-related and other factors as the Administrator may deem relevant. In no event shall an importer's offering prices in the United States be considered if they are lower than those prevailing in the foreign market or markets from which the importer is obtaining his/her supply;

(4) The existence of competitive restraints imposed upon domestic manufacturers by governmental regulations; and

(5) Such other factors as may be relevant to the determinations required under this paragraph.

(e) In considering the scope of the domestic market, consideration shall be given to substitute products which are reasonably interchangeable in terms of price, quality and use.

(f) The fact that the number of existing manufacturers is small shall not demonstrate, in and of itself, that adequate competition among them does not exist.

[62 FR 13953, Mar. 24, 1997, as amended at 81 FR 97019, Dec. 30, 2016]

§ 1301.35 Certificate of registration; denial of registration.

(a) The Administrator shall issue a Certificate of Registration (DEA Form 223) to an applicant if the issuance of registration or reregistration is required under the applicable provisions of sections 303 or 1008 of the Act (21 U.S.C. 823 and 958). In the event that the issuance of registration or rereg-

istration is not required, the Administrator shall deny the application. Before denying any application, the Administrator shall issue an order to show cause pursuant to § 1301.37 and, if requested by the applicant, shall hold a hearing on the application pursuant to § 1301.41.

(b) If in response to a show cause order a hearing is requested by an applicant for registration or reregistration to manufacture in bulk a basic class of controlled substance listed in Schedule I or II, notice that a hearing has been requested shall be published in the FEDERAL REGISTER and shall be mailed simultaneously to the applicant and to all persons to whom notice of the application was mailed. Any person entitled to file comments or objections to the issuance of the proposed registration pursuant to § 1301.33(a) may participate in the hearing by filing notice of appearance in accordance with § 1301.43. Such persons shall have 30 days to file a notice of appearance after the date of publication of the notice of a request for a hearing in the FEDERAL REGISTER.

(c) The Certificate of Registration (DEA Form 223) shall contain the name, address, and registration number of the registrant, the activity authorized by the registration, the schedules and/or Administration Controlled Substances Code Number (as set forth in part 1308 of this chapter) of the controlled substances which the registrant is authorized to handle, the amount of fee paid (or exemption), and the expiration date of the registration. The registrant shall maintain the certificate of registration at the registered location in a readily retrievable manner and shall permit inspection of the certificate by any official, agent or employee of the Administration or of any Federal, State, or local agency engaged in enforcement of laws relating to controlled substances.

[62 FR 13954, Mar. 24, 1997]

§ 1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

(a) For any registration issued under section 303 of the Act (21 U.S.C. 823), the Administrator may: